UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

DORA KLOBUS, ET AL.,

Plaintiffs,

v.

AKERO THERAPEUTICS, INC., ET AL.,

Defendants.

Case No.: 4:24-CV-2534-YGR

ORDER GRANTING MOTION TO DISMISS SECOND AMENDED COMPLAINT

Re: Dkt. No. 61

On May 5, 2025, the Court granted defendants' motion to dismiss plaintiff's first amended complaint with leave to amend. Plaintiffs have so amended and defendants move once again to dismiss. Having carefully considered the papers submitted and the pleadings in this action, and for the reasons set forth below, the Court hereby **GRANTS** the motion to dismiss without leave to amend.[1]

I. BACKGROUND

The Court presumes familiarity with the facts of this case. In its prior order, the Court found plaintiffs had met their burden to adequately allege loss causation and the existence of materially

[1] The parties have also filed numerous requests for judicial notice or to incorporate various exhibits by reference into the complaint. Defendants request notice be taken of six exhibits: the final SYMMETRY study protocol (Ex. 1), two press releases (Exs. 2 and 5), historical stock data for AKRO (Ex. 3), an October 2024 Form 8-K (Ex. 4), and an analyst report (Ex. 6). Plaintiffs do not contest notice of defendants' Exs. 4 and 6, which they acknowledge are both incorporated into the operative complaint by reference. The Court will therefore **GRANT** the request to take notice of these exhibits, though not for the truth of the matters asserted therein.

Plaintiffs' sole exhibit, the original and final SYMMETRY protocols and a summary of amendments made between the two, includes the sum total of defendants' requested exhibit 1. Plaintiffs oppose defendants' request as to defendants' Exhibit 1, arguing incorporating only the final protocol without the summary amendments would be incomplete. As plaintiffs' sole requested exhibit necessarily contains the sum total of defendants' Exhibit 1, the Court will **GRANT** the requests as to both.

The request to incorporate the balance of defendants' proffered exhibits is **DENIED**, as the Court does not find these exhibits necessary to decide the motion.

false or misleading statements.[2] However, plaintiffs failed to meet their burden to adequately plead scienter. In short, the Court found:

> defendants' argument . . . compelling that troubling gaps persist in plaintiffs' logic: defendants always knew they would ultimately have to report SYMMETRY results in a detailed enough fashion to include the trial design. . . . Nor do plaintiffs answer the looming question of why defendants would accurately and honestly report the inclusion of cryptogenic patients when they did –36 weeks into a 96-week trial– as opposed to keeping it a secret throughout the trial period. . . . Furthermore, while not dispositive by itself, plaintiffs present none of the classic indicia of scienter upon which Courts frequently permit claims to survive. The complaint is devoid, for instance, of whistleblowers or confidential informants or allegations of insider trading.

(Dkt. No. 56, Order Granting Motion to Dismiss with Leave to Amend ("First Order") at 24.) The Court took further note of defendants' argument that the FDA's approval indicated their subjective and honestly-held belief that their statements during the class period were true, and noted that "while not dispositive by itself, the fact lends support to a holistic analysis in which defendants present the more compelling argument with regard to scienter." (*Id*. at 25.)

In amending their complaint, plaintiffs introduce new factual allegations to re-plead scienter. (Dkt. No. 58, Second Amended Class Action Complaint for Violations of Federal Securities Law ("SAC").) The Court focuses only on those factual allegations relative to scienter.

Plaintiffs now include in the SAC SYMMETRY's trial protocol, all versions of which became public in May 2025, which they allege is significant in several respects. (*See* SAC ¶¶ 59-65.)[3] First, it allegedly shows that SYMMETRY was always designed as a 36-week study, *not* a 96-week study as originally described.

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[2] Throughout their opposition, plaintiffs state that the Court made certain findings in its prior order. (*E.g.*, Dkt. No. 63, Lead Plaintiffs' Opposition to Defendants' Motion to Dismiss Second Amended Class Action Complaint ("Oppo.") at 1 ("This Court found that Akero . . . and the individual executive Defendants . . . made 'objectively false statements' . . . .").) The assertion fails to understand the Court's intentional nuance. The Court found plaintiffs had adequately alleged as much, but did not, and does not, make factual findings at this juncture.

[3] The SAC defines the trial protocol as follows:

> The SYMMETRY protocol contained a number of important provisions. Under "Objectives," the original SYMMETRY protocol described the sole, "primary objective" or primary endpoint of the study as "[t]o evaluate the effect of EFX compared to placebo on fibrosis regression in subjects with compensated cirrhosis due to NASH ***at Week 36***." According to the protocol, it was based on those 36-week results (i.e., not 96-week results), that Defendants intended to "seek alignment from the applicable regulatory authorities on the dose selected prior to clinical use." The protocol included the following timeline, clearly indicating that biopsies were to occur at screening (the first blue triangle in the below), that the primary endpoint was at 36 weeks, and that the remainder of the SYMMETRY was for a "Long-Term Follow-up" only[.] . . . To investors, Defendants described the 96-week study period as a "Long-Term ***Safety*** Follow-Up," and thus not related to measurement of the trial's primary endpoint.

(*Id*. ¶ 62 and n.7 (quoting Dkt. No. 63-2) (emphases in original).) Plaintiffs argue this demonstrates the implausibility of defendant's proffered narrative in the earlier round of briefing that defendants had no intention to mislead because they voluntarily provided more detail than they needed when reporting "interim" results of the study.

Second, plaintiffs find significance in a change made to the first amended protocol, published on October 15, 2021. Plaintiffs submit a table that summarizes changes made to the protocol throughout all six published versions. The first revision "[a]ligned [the] protocol with US FDA recommendations, including revising stratification to include a maximum of approximately 20% of subjects with cryptogenic cirrhosis presumed secondary to [N]ASH." (Dkt. No. 63-2 at

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> Every clinical trial must be conducted according to a clinical trial protocol which is "[a] document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents." U.S. Dep't of Health & Hum. Servs., E6(R2) *Good Clinical Practice: Integrated Addendum to ICH E6(R1), Guidance for Industry*, §1.44 (Mar. 2018). The sponsor of the clinical trial, here Akero, is responsible for designing the protocol. *Id*., §5.4.1. The trial's protocol is to include, inter alia, patient inclusion and exclusion criteria, a specific statement of the endpoints to be measured during the trial, and a description of the statistical methods to be employed." *Id.*, §§6.4, 6.5.1-6.5.2, 6.91.

(SAC ¶ 58.)

252.) As per plaintiffs, this shows defendants' knowledge that the difference between the two categories is material.

Third, plaintiffs note the original and final versions differ in that only the latter identifies cryptogenic cirrhotic patients by name. Whereas the original protocol listed inclusion criteria of "[b]iopsy-proven compensated cirrhosis (fibrosis stage 4) due to definitive *or presumed* NASH," the final version listed "[b]iopsy-proven compensated cirrhosis (fibrosis stage 4) due to definitive NASH *or cryptogenic cirrhosis presumed secondary to* NASH (*Compare* Dkt. No. 63-2 at 48, *with id*. at 120 (emphasis supplied).)[4] Related to this change are revisions made to the appendices wherein the original defining term "Presumed NASH" was changed to "Cryptogenic Cirrhosis Presumed Secondary to NASH," Appendix F in the original vs. Appendix G in the final, as shown below.

Original Protocol

Definitive NASH	Presumed NASH
Histologic evidence of steatohepatitis with a NAS ≥ 3 and ≥ 1 point each in steatosis, lobular inflammation, and ballooning	No clear evidence of steatosis or steatohepatitis on histology (potentially due to burn-out), but no evidence of competing etiology and one of the following: previous history or presence of T2D or 2 out of 4 components of metabolic syndrome (obesity, dyslipidemia, elevated blood pressure, elevated fasting glucose)

[4] The SAC implies that this inclusion criteria language was added after the first revision, though the documents submitted provide only language in the first and the final protocols, along with the summary table. Thus, while it stands to reason that this language was added into the first amended protocol, since it tracks with the summary change cited above, the Court can only identify with certainty that this language was added at some point before the final version.

Final Protocol

Definitive NASH	Cryptogenic Cirrhosis Presumed Secondary to NASH
Histologic evidence of steatohepatitis with a NAS ≥ 3 and ≥ 1 point each in steatosis, lobular inflammation, and ballooning	No clear evidence of steatosis or steatohepatitis on histology (potentially due to burn-out), but no evidence of competing etiology and one of the following: previous history or presence of T2D or 2 out of 4 components of metabolic syndrome (obesity, dyslipidemia, elevated blood pressure, elevated fasting glucose)

(*Compare id*. at 111, *with id.* at 251.) In addition to further confirming defendants' knowledge of the material difference between the two, plaintiffs allege this shows that:

> when Defendants used the phrases "biopsy-proven" and "biopsy-confirmed" to describe the certainty of a diagnosis of NASH, by their own understanding, they communicated that Akero was enrolling patients with "Definitive NASH," and not "cryptogenic cirrhosis presumed secondary to NASH," the latter of which was a phrase they never used during the Class Period or prior to the completion of SYMMETRY's primary endpoint.

(SAC ¶ 64.)

Fourth, and finally, plaintiffs allege there is significance in the protocol's inclusion of subcategories among SYMMETRY patients beyond the definitive NASH and cryptogenic Cirrhosis subgroups.

> Further reflecting the material distinction between NASH cirrhosis and cryptogenic cirrhosis, the protocol provided that patients "will be stratified by T2D [i.e., Type 2 diabetes] status (Yes vs No) and diagnosis of cryptogenic cirrhosis presumed secondary to NASH (Yes vs No) at baseline" and that the "Primary Efficacy Analysis" to be conducted at Week 36 would be "adjust[ed] for [those] stratification factors."

(SAC ¶ 63 n.9.) Plaintiffs relatedly allege that study record versions of SYMMETRY posted on government websites did not mention cryptogenic cirrhotic subjects, but *did* mention stratification by other subgroups, namely, participants with diabetes and in another subgroup, Cohort D. (*See id.* ¶ 104.) Indeed, plaintiffs allege, defendants "enrolled more patients with cryptogenic cirrhosis in the main SYMMETRY study than they enrolled total patients in the Cohort D subgroup, yet disclosed only the latter, and not the former." (*Id.*)

II. ANALYSIS

A. Scienter Standard

The Court first addresses the standard under which it evaluates scienter at the pleading stage. Plaintiffs point the Court to the dual inquiry explained in *Glazer Cap. Mgmt., L.P., Forescout Techs., Inc.* 63 F.4th 747, 766. (9th Cir. 2023). Under this approach:

> [the] court conducts a dual inquiry when assessing whether the strong inference standard is met: first, it determines whether any one of the plaintiff's allegations is alone sufficient to give rise to a strong inference of scienter; second, if no individual allegations are sufficient, it conducts a holistic review to determine whether the allegations combine to give rise to a strong inference of scienter.

Id. (internal citation omitted). Plaintiffs assert that under this approach, a finding that "defendants knew their statements were false, or . . . that defendants were reckless as to the truth or falsity of their statement" can obviate the need for holistic review. (Oppo. at 9 (quoting *Mulderrig v. Amyris, Inc*., 492 F. Supp. 3d 999, 1024 (N.D. Cal. 2020).)

Further, "[a]n allegation that a defendant knew the truth but made a false public statement conclusively establishes that a defendant was, at a minimum, reckless as to the falsity of his or her statements." Plaintiffs rely on *Pampena v. Musk* for this proposition. (*See* Oppo. at 10 (citing 705 F.Supp.3d 1018, 1050-51 (N.D. Cal. 2023).) In that case, the court, relying on *Glazer*, found plaintiffs adequately pled scienter based, in part, on evidence that a defendant made repeated public statements contradicted by information to which he had access. Thus:

> What mattered for purposes of scienter [in *Glazer*] was that the defendants were aware of information—the acquirer's reconsideration of the merger—which rendered their statement about the merger misleading regardless of their alleged subjective belief that the merger would nevertheless happen. Here, even if Defendant made statements that were subjectively consistent with his beliefs about the Merger Agreement in the course of litigation (such as that the deal could not move forward if Twitter did not provide certain data), Plaintiffs allege facts raising a strong inference that he knew or recklessly disregarded the fact that he had material information (such as the waiver of due diligence) that would render his statements false or misleading.

Pampena, 705 F.Supp.3d at 1050-51 (emphasis in original).

Defendants counter that too much is made of *Pampena*. There, they note, the statements at issue were objectively and provably false, "akin to saying the sky is red, when it is, in fact, blue." (Dkt. No. 66, Defendants' Reply in Support of Motion to Dismiss Second Amended Complaint ("Reply") at 5.) Here, by contrast, defendants assert the Court's prior order found only that plaintiffs "adequately alleged that Defendants' descriptions of the overarching SYMMETRY patient population were misleading, not that they were false." (*Id*.) Defendants also point to the portion of the prior order holding that knowledge alone is insufficient to establish scienter. (*See id*. (citing First Order at 25 n.17).)

Ultimately, the Court takes guidance from the Ninth Circuit, which explained the standard thusly in *Glazer*:

> Scienter as used in the federal securities laws means the intent to mislead investors or deliberate recklessness to an obvious danger of misleading investors. Deliberate recklessness is a higher standard than mere recklessness and requires more than a motive to commit fraud. Rather, deliberate recklessness is an *extreme* departure from the standards of ordinary care . . . which presents a danger of misleading buyers or sellers that is either known to the defendant or is so *obvious* that the actor must have been aware of it. Recklessness only satisfies scienter under § 10(b) to the extent that it reflects some degree of intentional or conscious misconduct.

63 F.4th at 765 (cleaned up) (emphasis in original). Thus, under this standard, knowledge without intentional or conscious action designed to mislead is insufficient to plead scienter.

The Court further notes that it agrees with the *Pampena* court insofar as the opinion holds that a good-faith and subjective belief in the truth of one's own words cannot by itself overcome scienter allegations, where a defendant is plausibly alleged to have had access to information proving the objective falsity of their belief. To the extent plaintiffs assert that *Pampena* or any other in-circuit authority obviates the need for holistic review of the allegations based on knowledge of falsity alone, however, the Court disagrees.[5] Indeed, the *Pampena* court considered the allegations

[5] Plaintiffs' counsel asserted the contrary at oral argument. As support, they relied on both *Glazer* and *N.M. State Inv. Council v. Ernst & Young LLP*, 641 F.3d 1089 (9th Cir. 2011). In fact, both cases reaffirm that holistic review is necessary unless any single "allegation[], standing alone, [is] sufficient to create a strong inference of scienter." *Ernst & Young*, 641 F.3d at 1095. Though "deliberate recklessness" based on "more than a motive to commit fraud" can help inform the Court

in that portion of the opinion "holistically alongside Plaintiffs' other allegations of scienter." *Pampena*, 705 F. Supp. 3d at 1051.

Finally, the Court notes some guiding principles enumerated in *Glazer*. There, plaintiffs adequately pled scienter with respect to (ultimately false) statements about defendant company's strong performance, the experience of certain key employees, and expectations that a planned merger would successfully close. First, with regard to statements about the company's performance, plaintiffs alleged "a pressure campaign . . . to categorize deals as 'committed' even when they were not likely to close by payment." *Glazer*, 63 F.4th at 768. Each of these allegations were supported "with detailed factual allegations." *Id.* The Ninth Circuit found "[p]laintiffs' allegations of a company-wide pressure campaign, on their own, are sufficient to raise a strong inference of scienter" because the "[d]efendants must have known that deals were being miscategorized because the [i]ndividual [d]efendants themselves participated in the widespread pressure campaign to do so." *Id.* at 772. Allegations that defendants had access to information contradicting their public statements "bolstered" the scienter finding but the court "offer[ed] no opinion as to whether the access to information allegations, *on their own*, would support a strong inference of scienter." *Id.* at 773-74 & n.5 (emphasis supplied). Second, in the context of the statements as to the merger, the Court reads *Glazer* to reject the argument that subject belief operates as a "Get out Jail Free" card for securities fraud defendants. It does not read the opinion to demonstrate that knowledge alone pleads scienter absent circumstances showing the requisite mental state.

Ultimately, the Ninth Circuit has been clear that "[t]o meet the PSLRA's *high burden* for pleading scienter, a complaint cannot rely on 'mere motive and opportunity or recklessness, but rather, must state specific facts indicating no less than a degree of recklessness that *strongly*

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in deciding if any single allegation is sufficient, the case law does not hold what plaintiffs say it does, namely that "[s]cienter is established . . . if a complaint shows that the defendants knew their statements were false . . . ." (*See* Oppo. at 19 (internal citation omitted).) Plaintiffs read out of the scienter standard *Glazer*'s clear command, cited above, that "[r]ecklessness only satisfies scienter under § 10(b) to the extent that it reflects some degree of intentional or conscious misconduct." 63 F.4th at 765 (quoting *Nursing Home Pension Fund, Local 144 v. Oracle Corp*, 380 F.3d 1226, 1230 (9th Cir. 2004)).

suggests actual intent.'" *Prodanova v. H.C. Wainwright & Co., LLC*, 993 F.3d 1097, 1008 (9th Cir. 2021) (quoting *Glazer Cap. Mgmt., LP v. Magistri*, 549 F.3d 736, 743 (9th Cir. 2008) (emphases supplied).

B. Plaintiffs' Allegations

As an initial matter, the Court does not find plaintiffs raise an allegation that is sufficient by itself to render the holistic analysis unnecessary. At a minimum, defendants raise serious questions as to the cogency of plaintiffs' scienter theory. Whereas plaintiffs need no smoking gun, they cannot bypass the PSLRA's "formidable pleading requirements" by pleading actual knowledge alone. *See Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1055 (9th Cir. 2008).

Given the finding that none of the new allegations is sufficient, alone, to plead scienter, the Court analyzes plaintiff's reliance on the allegations of the protocol. Here, the Court notes that the allegations concerning defendants' actual knowledge that SYMMETRY included patients with cryptogenic cirrhosis were previously included in the FAC, as was the identification of SYMMETRY as a 36-week study. Even accepting plaintiffs' framing of the study's timeline, the Court fails to see how this alone strongly indicates an intent to mislead when defendants still had a 60-week "follow-up" period in which they could have stayed silent. Thus, the Court looks to the totality of the circumstances to see if plaintiffs adequately allege scienter.

Plaintiffs' theory is as follows:

Defendants badly needed money to fund Akero and undertook a sustained campaign to misinform investors as to SYMMETRY's study population in order to do so. Because the FDA required Akero to cap the participation of cryptogenic participants at a pre-specified level, this put them on notice as to the materiality of this subgroup's inclusion. In order to fund the company, Akero and the named defendants consistently omitted material information to investors throughout the class period when they did not specifically identify participants with cryptogenic cirrhosis until reporting results at the 36-week readout. The study protocol as originally written and amended: i) confirms knowledge that the distinction between the relevant subgroups was material, and ii) clarifies that the 36-week readout was not a reporting of interim results, but rather *the* final and heavily anticipated results of the study (new allegation). Additionally, study readouts reported the

existence of other subgroups, but declined to report the inclusion of patients with cryptogenic cirrhosis. At argument, plaintiff's counsel summarized defendants' actions at the week 36 mark as a choice to "cut their losses at that point."

The Court finds that the new allegations do not change the balance of the scienter equation. As defendants note, there are no allegations that plaintiffs *had to* report the relevant subgroup when they did.[6] If the intent were truly to mislead, defendants would likely have taken advantage of the remaining 60-week period in the study, even if it *were* simply a safety follow-up, to find a way out of their alleged conundrum.

Moreover, defendants argue that plaintiffs' theory effectively would impose a requirement that companies must disclose ***all*** information they share with the FDA or be subject to liability. While the Court does not understand plaintiffs to urge that perspective, the point in this context is well-taken. That the FDA considered it important to require specificity as to the subgroup breakdown does not *necessarily* mean defendants were under a legal duty to share those details.[7]

Plaintiffs also argue that the protocol provides evidence of contemporaneous knowledge that defendants' statements were false, and thus, classic indicia of scienter. In the context of the full set of allegations, though, the protocol does not add much. Plaintiffs previously pled that the study was designed to include two subgroups and that the divergence between the study's design and

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[6] *See* Reply at 2 ("Plaintiffs have not (and cannot) identify any legal basis for requiring Defendants to disclose the patient population at the 36-week mark or any particular time. Plaintiffs cite no FDA regulation requiring such disclosure, nor any other authority that might undercut what this Court observed— that Defendants ***voluntarily disclosed*** the SYMMETRY patient population, thereby undermining the notion that they intended to mislead investors.") (emphasis in original).

[7] Plaintiffs provide a quote from one analyst who asked a year and a half before the class period whether defendants' drug would prove successful on patients with "more advanced disease," (SAC ¶ 54), and another from J.P. Morgan that stated "***Importantly, SYMMETRY only enrolls patients with biopsy proven NASH***," (*id*., ¶ 131 (emphasis in original)). These demonstrate, plaintiff assert, that defendants were at least on notice that the market would consider the inclusion of patients with cryptogenic cirrhosis to be material. First, that a third-party analyst published a report says nothing about defendants' state of mind, nor can the Court impute those words to defendants. Second, these two quotes from analysts are simply not enough to demonstrate an "*extreme* departure from the [required] standards of ordinary care" needed to establish scienter on deliberate recklessness grounds, especially in the absence of a clearly identified legal obligation to disclose. *See Glazer*, 63 F.4th at 765.

defendants' public statements presented evidence of liability. (*See* Dkt. No. 58, First Amended Complaint ¶ 55(c)) (alleging that it was "materially false and misleading when . . . Defendants knew or deliberately disregarded and failed to disclose . . . that it was further "prespecified" in Akero's SYMMETRY trial design to exclude patients with cryptogenic cirrhosis from the calculation of the NASH resolution secondary endpoints."). The protocol itself does not answer the Court's questions from the last round of briefing: Why make misrepresentations when full disclosure was ultimately inevitable? Why choose a moment far earlier than required to voluntarily disclose the truth?

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The Court finds plaintiffs have failed to fill-in the logical gaps previously identified. In so finding, the Court is mindful of the Supreme Court's directive that inferences of scienter must be "cogent and compelling, thus strong in light of other explanations," *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007), and the Ninth Circuit's guidance that the facts alleged must "strongly suggest[] actual intent," *Prodanova*, 993 F.3d at 1008. Viewed holistically, the Court finds neither standard is met.

The Court has already provided plaintiffs one chance to amend the complaint and does not find that further amended would be likely to cure the deficiencies identified herein.

III. CONCLUSION

For the reasons set forth above, the motion to dismiss the Second Amended Complaint is **GRANTED WITHOUT LEAVE TO AMEND**.

The Clerk of the Court is ordered to close this case.

This terminates Docket No. 61.

IT IS SO ORDERED.

Date: August 15, 2025

YVONNE GONZALEZ ROGERS
UNITED STATES DISTRICT COURT JUDGE